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1802

DATE MAILED:

02/22/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/9/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), No days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 105, 107-115, 117-120 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 106 + 116 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 105, 107-115, 117-120 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or selection requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
see paper # 7
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☒ The proposed additional or substitute sheet(s) of drawings, filed on 9/30/92, has (have) been ☒ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The amendment filed November 9, 1993 (paper #11) is acknowledged and has been entered. Claims 106 and 116 have been cancelled. Claims 117-120 have been added. Claims 105, 107-115 and 117-120 are pending.

5 Claims 105, 107-115 and 117-120 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claims 105, 110-113 and 117 are confusing in reciting oligonucleotides "of different, known sequences" and "different oligonucleotides with known sequences" in predefined regions. Claims 109 and 114 are confusing in reciting oligonucleotides which are "at least 50% pure". It is unclear whether each "different" oligonucleotide is in a "different/predefined" region, i.e. a one-to-one relationship; or, whether multiple (e.g. 200) copies of the same oligonucleotide sequence are in a single predefined region, i.e. a
15 two hundred-to-one relationship; or, whether multiple (e.g. 200) oligonucleotides are in a single predefined region such that a defined number (e.g. 100 whether by design or experimental limitations) have the same nucleic acid sequence (e.g. "at least 50% pure"). An analogous criticism applies to claim 117.

20 The response (page 5) indicates the intent that "different" means individually different sequences, and not the number of molecules. However, the claims fail to convey a clear meaning of individual regions wherein each region comprises a "different" group of oligonucleotides such that each group consists of oligonucleotides of the same nucleic acid sequence. Furthermore,
25 assuming arguendo that were the case, then claims 109 and 114 would be totally

confusing since it would mean that as much as 50% of the oligonucleotides in a given group did not have the required nucleic acid sequence.

Claim 109 depends on a cancelled claim, i.e. claim 106.

Claim 120 should recite "The [substrate] array as recited in claim 117..." for proper antecedent basis.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure and failing to provide an adequate written description of the invention.

As to claims 109, 114 and 117-119, the specification is only enabled for substrates produced by light directed photolithographic synthesis using a matrix mask strategy. It would require undue experimentation to procure substrates providing the density of known, different oligonucleotide sequences in the claimed areal dimensions.

Claims 107-108 are rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 105 requires an area of less than about 0.01 cm^2 , i.e. less than about 10^{-4} m^2 . Claim 107 increases that area to less than about $10000 \text{ } \mu\text{m}^2$, i.e. less than about 10^{-2} m^2 ; while claim 108 recites the same area limitation of less than about $100 \text{ } \mu\text{m}^2$, i.e. less than about 10^{-4} m^2 .

The text of those sections of Title 35, U.S. Code not included in this

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action can be found in a prior Office action.

The rejection of claims 105-107, 109 and 114 under 35 U.S.C. § 102(b) as being clearly anticipated by Bio-Rad Catalogue M 1987 is withdrawn in view of applicants' amendments and arguments.

5 The rejection of claims 105-106, 109 and 114 under 35 U.S.C. § 102(b) as being clearly anticipated by Hames & Higgins is withdrawn in view of applicants' amendments and arguments.

Neither Bio-Rad nor Hames & Higgins teach or suggest substrates having the claimed densities.

10 The rejection of claims 105-114 under 35 U.S.C. § 102(e) as being anticipated by Singer et al (US 4,888,278) is withdrawn in view of applicants' amendments and arguments.

15 The rejection of claims 105-109 and 114-116 under 35 U.S.C. § 102(e) as being anticipated by Schwartz (US 4,886,741) is withdrawn in view of applicants' amendments and arguments.

Neither Singer et al nor Schwartz et al teach or suggest different, known oligonucleotides at known locations on a substrate; or, covalent coupling to a substrate in such predefined areas as claimed.

20 The rejection of claims 115-116 under 35 U.S.C. § 103 as being unpatentable over Hames & Higgins in view of either Koester et al (US 4,923,901) or Koester et al (US 4,923,901) and Guire (US 4,973,493) is withdrawn in view of applicants' amendments and arguments supra in regard to Hames & Higgins.

25 In conclusion, applicants' amendments and arguments filed November 9, 1993 have been fully considered but are not deemed convincing of patentability

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for the reasons supra and for other reasons already of record.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol A. Spiegel whose telephone number is (703) 308-3986.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Carol A. Spiegel

Carol A. Spiegel
CAROL A. SPIEGEL
PATENT EXAMINER
JAN 10 1991